

California Stem Cell Agency Appoints New President and Invests in Additional Alpha Clinics and Clinical Trials Targeting Cancer, Diabetes and Kidney Disease

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September 28th, 2017, Oakland, CA –

Maria Millan M.D. was today appointed as the new President and CEO of the California Institute for Regenerative Medicine (CIRM) by the CIRM governing Board.

Dr. Millan, who had been serving as interim President/CEO, joined CIRM in 2012 and was instrumental in the development of CIRM's infrastructure programs including the Alpha Stem Cell Clinics Network and the agency's Strategic Plan, that lays out the goals for the agency over the next few years. Prior to taking over as President, Dr. Millan was the Vice President of Therapeutics at CIRM and has helped the agency fund 23 new clinical trials since the beginning of 2016.

"CIRM is very fortunate to have Dr. Millan as its new President and CEO," said Jonathan Thomas, Ph.D., J.D., Chair of CIRM's governing Board. "She checks all the boxes for what our agency needs to achieve our mission of accelerating treatments to patients with unmet needs. Maria has an "all-in" attitude that is clearly visible in everything she does at CIRM and is why we chose her as our new leader. The Board and I are confident that she will lead our agency with great distinction."

Dr. Millan has a career devoted to improving patient lives. She is an organ transplant surgeon and researcher and served as an Associate Professor of Surgery and Director of the Pediatric Organ Transplant Program at Stanford. Dr. Millan was also the Vice President and Chief Medical Officer at StemCells, Inc. before coming to CIRM.

"I joined the CIRM team because I wanted to make a difference in the lives of patients," said Dr. Millan. "They are the reason why CIRM exists and why we fund stem cell research. I am humbled and very honored to be CIRM's President and look forward to further implementing our agency's Strategic Plan in the coming years."

Dr. Millan replaces former President Randal Mills, Ph.D., who left the agency in June of 2017.

The Board also voted to fund two new Alpha Stem Cell Clinics. The CIRM Alpha Stem Cell Clinics are a network of leading California medical centers that conduct high quality stem cell trials in multiple disease areas for patients with unmet medical needs. In 2014, CIRM launched its first Alpha Clinics at the City of Hope, UC San Diego, and a joint clinic between UC Los Angeles and UC Irvine. In the past three years, the network has conducted 40 clinical trials covering 18 disease indications and have enrolled or treated over 200 patients.

Recognizing the success of the Alpha Clinics network, CIRM's Board set aside \$16 million to fund two additional Alpha Clinics at the University of California, Davis and the University of California, San Francisco. The two new locations are based in Northern California and will expand the network's outreach to more patients who are considering enrolling in stem cell trials.

"The Alpha Clinics are a one-of-a-kind network that gives patients access to the highest quality stem cell trials for a breadth of diseases including cancer, diabetes, heart disease and spinal cord injury," said Abba Creasey, Ph.D., CIRM's Senior Director of Strategic Clinical, Regulatory, and Infrastructure Programs. "We are excited about the Board's decision to fund two new Alpha Clinics. Expanding our network will allow more patients to participate in stem cell trials and will advance the development of stem cell treatments that could help or possibly cure patients."

Last but not least, the CIRM Board approved \$58.8 million in funding for five new clinical trials. This raises the total number of CIRM-funded trials to 40 since the agency's inception in 2004. As proposed in the agency's five-year Strategic Plan, this latest funding round also brings CIRM's goal of 50 new clinical trials by 2020 up to a total of 23.

Three of these newly funded trials target different types of cancers.

The Board awarded Dr. Christine Brown, at the City of Hope, \$12.8 million to fund a Phase 1 trial targeting an aggressive brain cancer

called malignant glioma. City of Hope will re-engineer a patient's immune system central memory T cells (TCM cells) to express chimeric antigen receptors (CAR). These CAR-T cells will recognize a molecular marker on the surface of glioma cancer stem cells and kill the tumors. Dr. Brown's award to pursue CAR-T therapy for solid cancers comes at an exciting and opportune time with the recent U.S. Food and Drug Administration (FDA) approval of the first CAR-T therapy, called Kymriah, for patients with acute lymphoblastic leukemia, a deadly form of blood cancer.

Nohla Therapeutics Inc. received \$6.9 million for a Phase 2 trial testing a hematopoietic stem cell and progenitor cell therapy to help patients suffering from neutropenia, a condition that leaves people susceptible to deadly infections, after receiving chemotherapy for acute myeloid leukemia.

Forty Seven Inc. received \$5 million in funding for a Phase 1b clinical trial treating acute myeloid leukemia. The team is using a combination of a monoclonal antibody and the drug Azacitidine to make the leukemia stem cells vulnerable to being attacked and destroyed by the immune system.

The other two trials are targeting diabetes and end stage kidney failure.

ViaCyte was awarded \$20 million to fund a Phase 1/2 clinical trial to test its PEC-Direct (a.k.a. VC-02) islet cell replacement therapy for high-risk type 1 diabetes. The company is using a small, implantable device containing pancreatic progenitor cells derived from human embryonic stem cells. After implantation, these cells develop into the kind of cells destroyed in type 1 diabetes. Blood vessels are able to grow into the device to provide blood flow to the implanted cells which, in turn, detect blood sugar levels and secrete insulin and other hormones to help restore blood sugar to healthy levels.

Humacyte Inc. received \$14.1 million to fund a Phase 3 trial that is comparing the performance of its acellular bioengineered vessel with the current standard of dialysis treatment for kidney disease patients to determine if the bioengineered vessel is superior in remaining open for longer periods of time and with lower incidence of interventions due to blood clots and infections.

The Board also approved \$5.2 million in funding for a late stage preclinical project led by Dr. Matthew Porteus at Stanford University. The team is using genome editing technology to correct the sickle cell disease mutation in hematopoietic, or blood-forming stem cells, to treat patients with sickle cell disease. The team hopes to complete the final experiments required for them to file an Investigational New Drug (IND) application with the FDA so they can be approved to start a clinical trial.

About CIRM

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information go to <http://www.cirm.ca.gov/>

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